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— *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))*

— *of inventorship (Rule 4.17(iv))*

[Continued on next page]

(54) Title: TRACHEAL TUBES

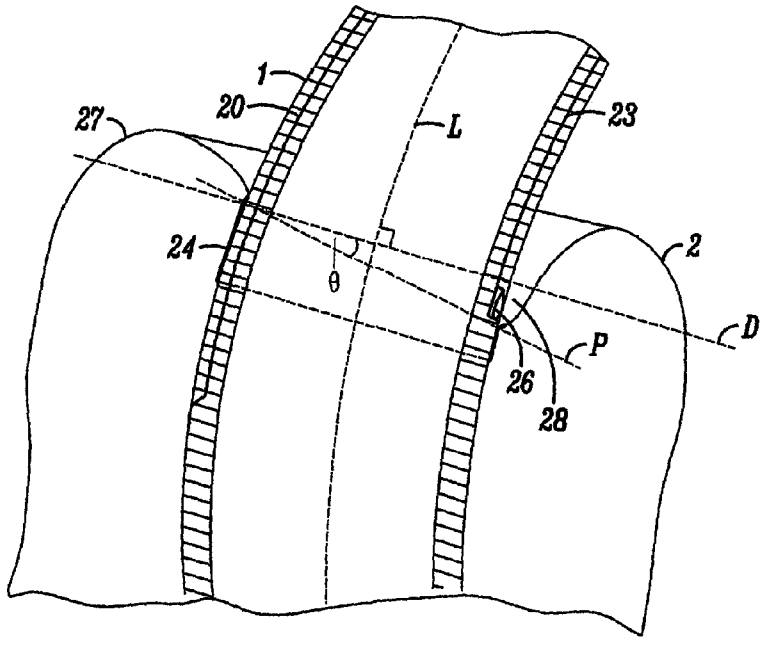


FIG. 2

(57) Abstract: The inflatable sealing cuff (2) at the patient end (3) of a tracheostomy tube is attached with the shaft (1) of the tube by two collars (24 and 25) turned inside out within the cuff. The upper collar (24) is attached with the shaft (1) along a line of locus in a plane P that is inclined to the diametrical plane D at an angle of between 5° and 45° so that secretions collect preferentially in a region around the opening (26) of a suction lumen (23). The shaft (1) is curved and the suction opening (26) is located on the inside of the curve, the upper end (27) of the cuff (2) being profiled to form a recess (28) in the region of the suction opening into which the secretions can flow.

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TRACHEAL TUBES

This invention relates to tracheal tubes of the kind having a shaft, a sealing cuff extending around and attached with the shaft in the region of the patient end, a suction lumen extending along the shaft and having a suction opening in the region above where the cuff is attached with the shaft.

Cuffed tracheal tubes, in particular, tracheostomy tubes, can present a problem in that secretions produced in the trachea may collect outside the tube above the cuff, providing a site for the accumulation of bacteria and infection.

Various proposals have been made previously for removing such secretions by suctioning from above the cuff. US 4607635 describes a tracheal tube having a channel open at various locations along its length and through which a suction catheter can be inserted to remove secretions at any desired location above the cuff. In US 4305392 there is described a tracheal tube with a bulbous chamber above the cuff in which secretions are collected for removal through a suction lumen extending through the wall of the tube. US 4840173 describes a catheter having a suction tube projecting over the proximal collar of the cuff to increase the amount of secretions that can be collected. GB 2250440 describes a tube where the upper end of the cuff is everted within the cuff so that it does not provide any obstruction to locating a suction opening as close as possible to the cuff. JP-A-10005340 describes a tube with two suction lumens linked by a gutter where they open on the side of the tube. US6796309 describes a tracheal tube with a gutter extending around the tube from the suction opening.

One difficulty with previous tubes is in ensuring that the maximum amount of secretions is removed.

It is an object of the present invention to provide an alternative tracheal tube.

According to the present invention there is provided a tracheal tube of the above-specified kind, characterised in that the configuration of the upper end of the cuff is arranged

such that secretions collecting above the cuff collect preferentially in a region around the suction opening.

The upper end of the cuff is preferably attached with the outside of the shaft along a line the locus that lies in a plane inclined at an angle away from the diametrical plane at right angles to the longitudinal axis of the shaft. The plane including the line of locus of attachment may be inclined at an angle between 5° and 45° to the diametrical plane. The cuff may be attached with the shaft at its upper end by a collar that is turned inside out to lie inside the cuff and may be attached at its lower end by a collar that is turned inside out to lie inside the cuff. The shaft is preferably curved along its length, the suction opening being located towards the inside of the curve. The sealing cuff may be an inflatable sealing cuff. The tube may have an inflation lumen extending along the shaft and displaced from the suction lumen on an opposite side of the shaft. The upper end of the cuff is preferably profiled to form a recess into which secretions can flow, the recess being located towards one side of the shaft in the region of the suction opening. The tube is preferably a tracheostomy tube, its patient end being adapted to locate in the trachea and its machine end being adapted to extend through a surgically made opening in the throat.

A tracheostomy tube according to the present invention will now be described, by way of example, with reference to the accompanying drawing, in which:

Figure 1 is a side elevation view of the tube; and

Figure 2 is an enlarged sectional view of a part of the tube in the region of the upper end of the cuff;

The tube includes a tubular shaft 1 curved along its length and having an inflatable sealing cuff 2 towards its patient end 3, which is adapted to locate in the trachea. The rear or machine end 6 of the tube is adapted to extend through a surgically made opening in the patient's throat and has a flange 4 by which the tube is secured about the neck and a coupling 5 by which gas connection can be made to the tube. The shaft 1, flange 4 and coupling 5 may

be integrally moulded with one another as a single piece from a plastics material, such as PVC. The tube could alternatively be straight and flexible or formed in different shapes.

The cuff 2 is inflated by means of an inflation lumen 20 extending along the length of the shaft 1 within its wall along the outside of its curve and opening at one end into the interior of the cuff. The lumen 20 is connected to a small-bore inflation tube 21 close to the machine end 6 of the tube. The machine end of the inflation tube 21 is terminated by a conventional connector and inflation indicator 22. The inflation lumen could, alternatively, be provided by a small-bore tube extending along the outside of the shaft and attached with it, such as in a channel along the shaft.

On its opposite side, along the inside of the curvature of the shaft 1, the tube has a suction lumen 23 extending parallel to the inflation lumen 20. The suction lumen 23 has a larger diameter than the inflation lumen 20 and extends within the wall of the shaft 1 although it could be provided by a separate tube extending in a semi-cylindrical channel moulded longitudinally along the outside surface of the shaft. At its rear, machine end the suction lumen 23 is connected with a suction tube 10 that is terminated by a coupling 11. In use, the coupling 11 is connected with a suction source (not shown) such as a syringe or suction pump.

The cuff 2 is of a thin plastics material moulded to its desired inflated shape, which is a generally doughnut shape. The cuff 2 has two collars 24 and 25 at opposite ends by which the cuff is attached to the outside of the shaft 1. The collars 24 and 25 are turned inside out, in the manner described in US5201310, so that the collars do not extend beyond the inflated part of the cuff. In conventional cuffed tubes the line of attachment of the upper collar with the shaft lies in a plane extending orthogonally to the longitudinal axis of the tube. In the present invention, by contrast, the upper end of the cuff (that is, the end away from the patient end of the tube) 2 is attached with the shaft 1 by means of its upper end collar 24 along a line lying in a plane "P" that is inclined at an angle θ to the diametrical plane "D" that extends orthogonally to the longitudinal axis "L" of the tube. The angle θ is preferably between about 5° and 45°. The angle is such that the lowest point of attachment of the collar 24 (with the

longitudinal axis "L" at the patient end 3 vertical) is on the inside of the curve of the shaft 1, in alignment with the opening 26 of the suction lumen 23.

It will be appreciated that the inclined line of attachment of the cuff 2 with the shaft 1 encourages secretions collecting above the cuff to flow to the lowest point and to the region of the suction lumen opening 26. In this way, even small volumes of secretions, that might in conventional tubes be insufficient to flow to the suction lumen opening, will flow to the region of the suction opening 26 and collect there in sufficient quantities to be removed freely.

It is preferable to shape the upper part 27 of the cuff 2 so that the region of the cuff around the suction lumen opening 26 is spaced from the shaft 1 by a greater distance than other regions of the cuff, forming a small sump 28 in which the secretions can collect for suctioning. In order to maintain this spacing it may be advantageous to form the outer surface of the shaft 1 in the region of the opening 26 with a suitable profile such as shallow projections or channels.

The arrangement of the present invention can enable a greater proportion of secretions to be removed.

The sealing cuff on the tube need not be of the kind that is inflated and deflated with a gas but could, instead, for example, be of a self-expanding kind, such as including a foam material, or formed of flanges, gills or the like.

It will be appreciated that the invention is not confined to tracheostomy tubes but could be used in other tracheal tubes.

CLAIMS

1. A tracheal tube having a shaft (1), a sealing cuff (2) extending around and attached with the shaft in the region of the patient end (3), a suction lumen (23) extending along the shaft and having a suction opening (26) in the region above where the cuff (2) is attached with the shaft (1), characterised in that the configuration of the upper end of the cuff (2) is arranged such that secretions collecting above the cuff collect preferentially in a region around the suction opening (26).

2. A tracheal tube according to Claim 1, characterised in that the upper end (27) of the cuff (2) is attached with the outside of the shaft (1) along a line of locus that lies in a plane (P) inclined at an angle (θ) away from the diametrical plane (D) at right angles to the longitudinal axis (L) of the shaft (1).

3. A tracheal tube according to Claim 2, characterised in that the plane (P) including the line of locus of attachment is inclined at an angle (θ) between 5° and 45° to the diametrical plane (D).

4. A tracheal tube according to any one of the preceding claims, characterised in that the cuff (2) is attached with the shaft (1) at its upper end by a collar (24) that is turned inside out to lie inside the cuff.

5. A tracheal tube according to any one of the preceding claims, characterised in that the cuff (2) is attached at its lower end by a collar (25) that is turned inside out to lie inside the cuff.

6. A tracheal tube according to any one of the preceding claims, characterised in that the shaft (1) is curved along its length and that the suction opening (26) is located towards the inside of the curve.

7. A tracheal tube according to any one of the preceding claims, characterised in that the sealing cuff is an inflatable sealing cuff (2).

8. A tracheal tube according to Claim 7, characterised in that the tube has an inflation lumen (20) extending along the shaft (1) and displaced from the suction lumen (23) on an opposite side of the shaft.

9. A tracheal tube according to any one of the preceding claims, characterised in that the upper end (27) of the cuff (2) is profiled to form a recess (28) into which secretions can flow and that the recess (28) is located towards one side of the shaft (1) in the region of the suction opening (26).

10. A tracheal tube according to any one of the preceding claims, characterised in that the tube is a tracheostomy tube, and that its patient end (3) is adapted to locate in the trachea and its machine (6) end is adapted to extend through a surgically made opening in the throat.

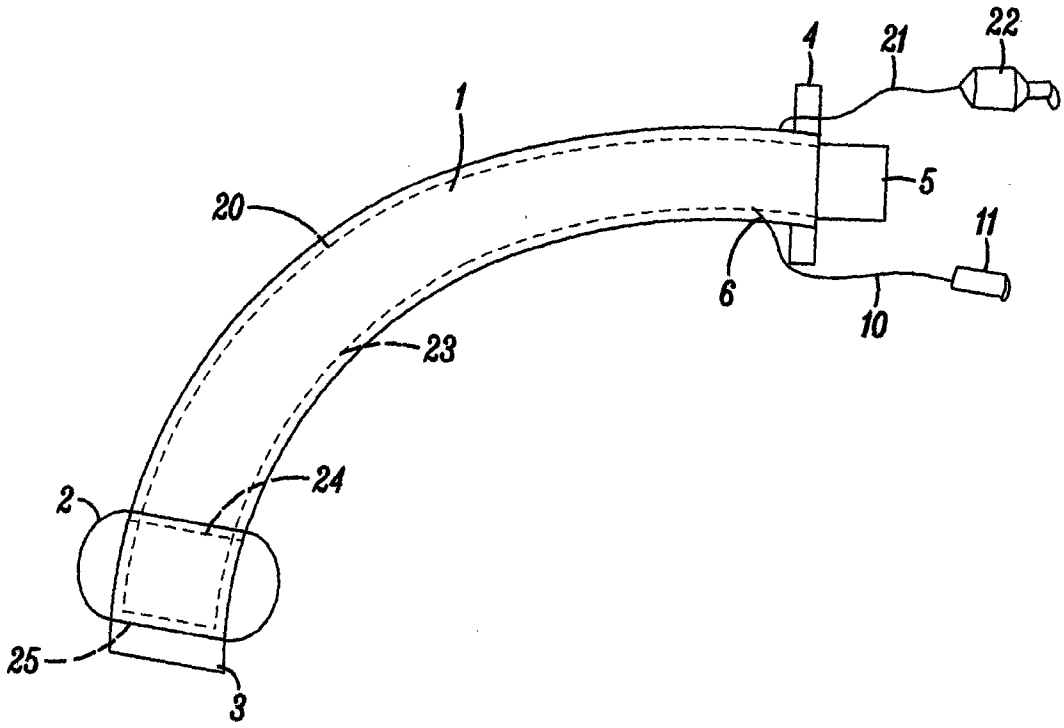


FIG. 1

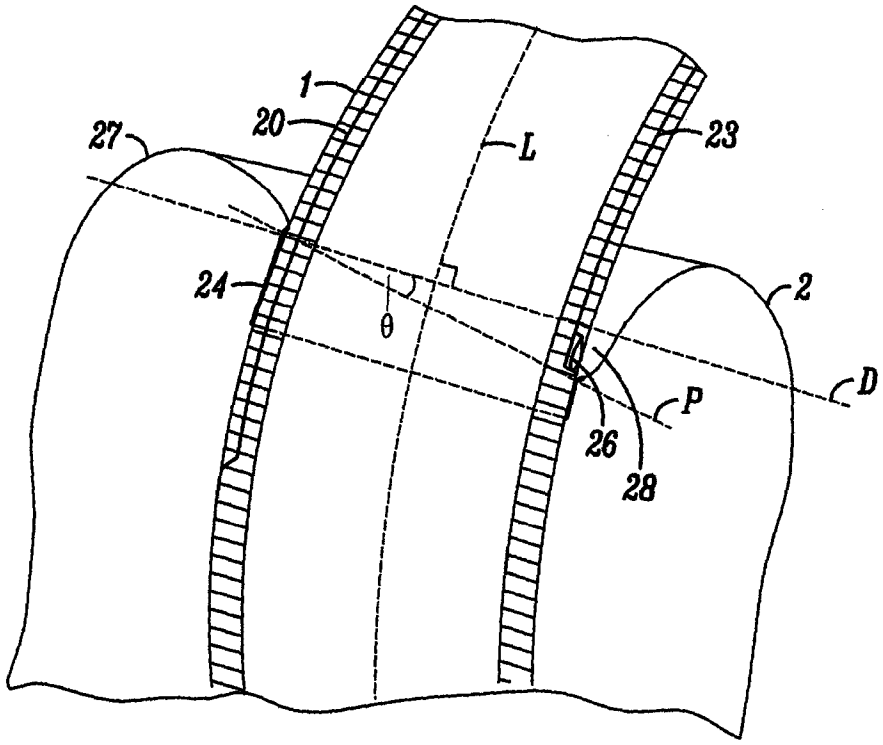


FIG. 2

INTERNATIONAL SEARCH REPORT

International application No
PCT/GB2014/000511

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61M16/04
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2012/087839 A1 (BARD INC C R [US]; NISHTALA VASU [US]; CICCONE PAUL [US]; TERRY RICHAR) 28 June 2012 (2012-06-28)	1-3,6-10
Y	abstract; figures 1-4 paragraphs [0052], [0053], [0055] - [0058]	4,5

X	WO 2012/087837 A1 (BARD INC C R [US]; NISHTALA VASU [US]; CICCONE PAUL [US]; TERRY RICHAR) 28 June 2012 (2012-06-28)	1-3,6,7, 9,10
Y	abstract; figures 4,5,10,11 paragraphs [0048], [0051], [0058], [0059]	4,5

X	US 2004/255951 A1 (GREY CHRISTOPHER [US]) 23 December 2004 (2004-12-23)	1-3,6,7, 9,10
Y	abstract; figures 1-5 paragraphs [0048], [0050], [0052]	4,5

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[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
17 March 2015	23/03/2015

Name and mailing address of the ISA/	Authorized officer
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C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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A	US 2008/053454 A1 (PASILLAS PEDRO VELAZCO [MX] ET AL) 6 March 2008 (2008-03-06) the whole document -----	4,5

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
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